UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

MARY MILANA and VICTOR MILANA,

Plaintiffs,

v. Case No: 8:21-cv-831-CEH-AEP

EISAI, INC. and ARENA PHARMACEUTICALS, INC.

Defendants.
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ORDER

This cause comes before the Court upon Defendant Eisai, Inc.'s Partial Motion to Dismiss Plaintiffs' Complaint (Doc. 19) and Defendant Arena Pharmaceuticals, Inc.'s Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(6) and 9(b) (Doc. 21). Plaintiffs Mary Milana and Victor Milana respond in opposition (Doc. 31). Eisai and Arena reply (Docs. 39, 40).

This products-liability action centers on a prescription drug named Belviq. Mary Milana alleges that this prescription drug gave her breast cancer. She and her husband now sue Eisai, Inc., and Arena Pharmaceuticals, Inc., under state law. Eisai and Arena move for dismissal under Rule 12(b)(6). For the reasons set forth below, the Court will grant-in-part and deny-in-part Eisai's Partial Motion to Dismiss and deny Arena's Motion to Dismiss.

I. FACTUAL BACKGROUND[1]

Mary Milana took Belviq from 2013 through 2020. Doc. 1 ¶15. Also known as lorcaserin hydrochloride, Belviq is a first-in-class oral selective serotonin 5HT2c receptor agonist. *Id.* at ¶¶2, 63. The Food and Drug Administration initially approved Belviq in 2012 as "an adjunct to reduced-calorie diet and increased physical activity for chronic weight management" in adult patients whose body mass index exceeds, or is equal to, 30kg/m^2 or adult patients whose body mass index exceeds, or is equal to, 27kg/m^2, with at least one weight-related comorbid condition. *Id.* at ¶48. Available by prescription only, users may take a 10mg dose twice per day or take one 20mg extended-release dose daily. *Id.* at ¶63. Dr. Wei Kao, Mary's primary-care physician, and his colleague, Dr. Gerard Squittiere, prescribed Belviq to Mary as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management. *Id.* at ¶¶2, 16. As a result of using Belviq, Mary was diagnosed with breast cancer in 2017. *Id.* at ¶17.

Eisai, Inc.'s business involved designing, researching, manufacturing, testing, advertising, promoting, marketing, selling, or distributing Belviq for the primary purpose of chronic weight management. *Id.* at ¶¶22, 26, 46. Similarly, Arena Pharmaceuticals, Inc.'s business involved designing, researching, manufacturing, testing, labeling, advertising, promoting, marketing, selling, or distributing Belviq for chronic weight management. *Id.* at ¶¶38, 46.

[1] The facts are derived from the complaint, the factual allegations of which the Court must accept as true in ruling on the motions. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007).

Before receiving the FDA's approval, Belviq underwent trials. First, during the preclinical trial program for Belviq, Eisai and Arena conducted a two-year carcinogenic study in rats. *Id.* at ¶64. This study identified lorcaserin as a non-genotoxic carcinogen that induced multiple types of tumors. *Id.* This identification resulted primarily from an increase in mammary tumors in both sexes near clinical exposure and in female rates at all doses. *Id.* The study also revealed an increase in astrocytomas, malignant schwannomas, hepatocellular adenoma and carcinoma, skin subcutis fibroma, skim squamous carcinoma, and breast follicular cell adenoma in male rates. *Id.* at ¶65. Second, Eisai and Arena conducted a two-year carcinogenicity study in mice during the preclinical trial program, which demonstrated an increase in malignant hepatocellular carcinoma in male mice and schwannoma in female mice. *Id.* at ¶68.

Third, between 2006 and 2009, Eisai and Arena conducted the Behavioral Modification and Lorcaserin for Overweight and Obesity Management Trial, known as the "BLOOM trial," to examine the efficacy of lorcaserin in reducing body weight. *Id.* at ¶72. Fourth, Eisai and Arena conducted the Behavioral Modification and Lorcaserin Second Student for Obesity Management Trial, known as the "BLOSSOM trial," to study the effects of lorcaserin on body weight, cardiovascular risk, and safety. *Id.* at ¶73. Because data from the BLOOM trial and the BLOSSOM trial revealed only a 3.3% mean weight loss after one year with lorcaserin over that of the placebo groups, lorcaserin failed to meet the mean efficacy criterion of the FDA's obesity draft guidance. *Id.* at ¶74.

In December of 2009, Arena filed its new drug application for Belviq. *Id.* at ¶75. In September of 2010, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee, known as "EMDAC," met to discuss approval of Belviq based upon the results of the preclinical trials, the BLOOM trial, and the BLOSSOM trial. *Id.* at ¶76. Based upon concerns about the preclinical carcinogenicity findings and marginal weight loss, the EMDAC panel voted against approving Belviq because the potential benefits did not outweigh the potential risks. *Id.* The next month, the FDA rejected approval of Belviq, citing "uncertainty in diagnosis of mammary masses in rats, unresolved issues with the exposure-response relationship between lorcaserin and mammary adenocarcinoma, failure to identify a mode of action and a clear safety margin for brain astrocytoma, and marginal weight loss." *Id.* at ¶77.

In response to the rejection, Eisai and Arena convened a pathology working group to blindly readjudicate the preclinical mammary tumor data in rats. *Id.* at ¶78. As to this readjudication, while the number of adenocarcinoma decreased in the lorcaserin group compared to the control group, lorcaserin still increased the incidence, tumor onset and multiplicity, and the lethality of mammary adenocarcinoma, with the high-dose lorcaserin group maintaining a statistically significant increase in adenocarcinomas compared to the control group. *Id.* at ¶83.

From December 2007 to August 2010, Eisai and Arena conducted the Behavioral Modification and Lorcaserin for Obesity and Overweight Management in Diabetes Mellitus Trial, known as the "BLOOM-DM trial," to examine the efficacy and safety of lorcaserin for weight loss in patients with Type 2 Diabetes Mellitus. *Id.*

at ¶80. In December of 2011, in response to FDA's rejection, Eisai and Arena submitted the final report of the BLOOM-DM trial, data from the pathology working group's readjudication, and data from other studies. *Id.* at ¶81. In May of 2012, a second EDMAC panel met to discuss approval of Belviq with a focus on the pathology working group's readjudication of preclinical data to analyze the drug's potential carcinogenicity risk, to determine a safety margin for astrocytoma, and to discuss the results of the BLOOM-DM trial to determine efficacy. *Id.* at ¶85. The panel voted that the benefits of Belviq outweighed the risks for an overweight and obese population. *Id.* On June 26, 2012, FDA Deputy Division Director Dr. Eric Colman indicated in his summary review of the application that the pathology working group's analysis addressed the concerns about the original application and that he did not believe that Belviq posed a risk for mammary adenocarcinoma in humans. *Id.* at ¶86. However, he also noted that the FDA's pharmacology/toxicology reviewer concluded that the prolactin studies, while supportive of a plausible role of prolactin in tumor formation, fell short of definitive proof that elevated prolactin levels caused the increased tumors during the two-year carcinogenicity rat study. *Id.*

On June 27, 2012, the FDA approved Arena's application to market and sell Belviq. *Id.* at ¶48. Afterwards, Eisai and Arena jointly launched the drug in accordance with an agreement between them, entitled the "Amended and Restated Marketing and Supply Agreement." *Id.* at ¶49. Arena entered into the Amended and Restated Marketing and Supply Agreement with Eisai to establish a collaboration to support Belviq's development, approval, and commercialization. *Id.* at ¶51. Arena promoted

the safety, efficacy, and sale of Belviq through various public outlets, including its website, press releases, and the drug's label. *Id.* at ¶53.

From January 2014 to June of 2018, Eisai and Arena conducted the Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients – Thrombolysis in Myocardial Infarction 61 trial, which was a post-marketing trial of lorcaserin. *Id.* at ¶89. This trial, referred to as "CAMELLIA-TIMI 61 trial," evaluated the risk of heart-related issues with Belviq. *Id.* at ¶90.

On July 15, 2016, the FDA approved Arena's application to market and sell Belviq XR, an extended-release tablet of lorcaserin hydrochloride. *Id.* at ¶55. Eisai and Arena jointly launched Belviq XR in 2016 in accordance with the terms of an agreement between them, entitled the Second Amended and Restated Marketing and Supply Agreement, which they entered into in November of 2013. *Id.* at ¶56. Like the Amended and Restated Marketing and Supply Agreement, Arena entered into the Second Amended and Restated Marketing and Supply Agreement with Eisai to establish a collaboration to support Belviq's development, approval, and commercialization. *Id.* at ¶58.[2] In 2017, Eisai purchased the global rights to develop and market Belviq from Arena. *Id.* at ¶61.

In January of 2020, the FDA issued a safety notice about clinical trial results showing a possible increased risk of cancer with Belviq use. *Id.* at ¶91. On February 13, 2020, the FDA announced that Eisai had requested to voluntarily withdraw Belviq

[2] The Milanas refer to Belviq and Belviq XR collectively as "Belviq" in the complaint. Doc. 1 ¶55.

from the market. *Id.* at ¶92. According to the FDA, the CAMELLIA-TIMI 61 trial data indicated an imbalance of cancer in patients taking Belviq that increased with treatment duration, including pancreatic, colorectal, and lung cancer. *Id.* The FDA also instructed all healthcare professionals to cease prescribing Belviq and to contact their patients taking Belviq to inform them of the increased risk and to ask that they stop taking Belviq. *Id.*

II. PROCEDURAL DEVELOPMENT

Joined by her husband, Victor Milana, Mary now sues Eisai and Arena. The complaint contains these claims against Eisai and Arena: (1) negligence; (2) strict products liability under a defective design theory and a failure-to-warn theory; (3) breach of express warranty; (4) fraudulent misrepresentation and concealment; (5) negligent misrepresentation; and (6) loss of consortium. Doc. 1 ¶¶106–357. Eisai moves for partial dismissal, seeking dismissal of the negligence and strict-products-liability to the extent that the Milanas based those claims upon a defective design theory, the breach of express warranty claim, and the misrepresentation claims. Doc. 19 at 4–11. Arena joins in that motion, Doc. 20 at 1, and separately seeks dismissal of Counts I through V, Doc. 21 at 1–2. The Milanas respond in opposition (Doc. 31), to which Eisai and Arena reply (Docs. 39, 40). Finally, because the Milanas have voluntarily dismissed all claims against Eisai Co., Ltd., and Arena Pharmaceuticals GmbH, those parties are no longer parties to this action. Doc. 54 at 1.

III. LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6), a pleading must include a "short and plain statement of the claim showing that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009) (internal quotation marks omitted) (quoting Fed. R. Civ. P. 8(a)(2)). Labels, conclusions and formulaic recitations of the elements of a cause of action are not sufficient. *Id.* at 678 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Further, mere naked assertions are not sufficient. *Id.* A complaint must contain sufficient factual matter, which, if accepted as true, would "state a claim to relief that is plausible on its face." *Id.* (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citation omitted). However, the Court need not accept as true a legal conclusion stated as a "factual allegation" in the complaint. *Id.*

IV. DISCUSSION

Preliminarily, in responding to Eisai's Partial Motion to Dismiss and Arena's Motion to Dismiss, the Milanas explain that they "voluntarily withdraw[] their breach of express warranty claim." Doc. 31 at 2. As such, the Court need not analyze the arguments for dismissal of that claim. As discussed in further detail below, the Court will grant the Milanas leave to file an amended complaint. Because the Milanas seek to withdraw the breach-of-express-warranty claim, they must remove that claim when amending their complaint to the extent that they elect to amend.

Relatedly, Arena's three-page motion, which prior counsel filed, focuses heavily on the breach-of-express-warranty claim. Doc. 21 at 1–2. As to Counts I, II, IV, and V, Arena argues only that the Milanas "assert nothing more than threadbare assertions and conclusory allegations without enough specific facts to state a claim and therefore fail to meet minimum pleading standards as a matter of law." *Id.* at 1. This undeveloped argument, which lacks any supporting legal authority, is insufficient for dismissal under Rule 12(b)(6). Thus, because the Milanas seek to withdraw their breach-of-express-warranty claim and Arena's remaining arguments are insufficient for dismissal, the Court will deny Arena's motion.[3]

Having disposed of Arena's Motion to Dismiss, the Court turns to Eisai's Partial Motion to Dismiss. Eisai advances two arguments: (1) the Court must dismiss the negligence and strict-products-liability claims because the Milanas' conclusory allegations that Belviq was defectively designed do not satisfy pleading standards; and (2) the Court must dismiss the claims for fraudulent misrepresentation and concealment and for negligent misrepresentation because the Milanas' allegations do not comply with Rule 9(b). Doc. 19 at 4–8, 10–11.

A. The Milanas Plausibly Allege a Design Defect and Causation in Counts I (Negligence) and II (Strict Products Liability-Defective Design)

Eisai seeks dismissal of the negligence and strict-products-liability claims to the extent the complaint bases those claims upon a design-defect theory, arguing that the

[3] As mentioned above, Arena also joins in Eisai's Partial Motion to Dismiss. Doc. 20 at 1.

Milanas fail to identify a design defect in Belviq and that the complaint lacks allegations that any such defect caused, or could have caused, Mary's breast cancer. Doc. 19 at 4–8.[4] The Court disagrees.

Addressing Counts I and II together, Eisai argues that the Milanas fail to identify a design defect in Belviq. Doc. 19 at 6–7. Eisai asserts that courts applying Florida law typically use at least one of the following tests to determine whether a product is defectively designed: (1) the consumer-expectations test; (2) the risk-utility test; and (3) the reasonable-alternative-design test. *Id.* at 5.[5] Eisai contends that the Court need not determine whether the consumer-expectations test is the applicable test in resolving the Partial Motion to Dismiss because the Milanas fail to allege sufficient facts to state a design-defect claim under any of the three tests. *Id.* at 5–6 n.2. Indeed, Eisai argues that the complaint's allegations merely track the language of the various tests for determining a defect. *Id.* at 7. Eisai also argues that the complaint lacks allegations that identify any design defect that could have caused Mary's breast cancer or how such defect allegedly caused her breast cancer. *Id.* at 8.

[4] Eisai does not seek dismissal of the negligence or strict liability claims to the extent that the complaint bases those claims upon allegedly inadequate warnings. Doc. 19 at 2 n.1.

[5] Under the consumer-expectations test, a product is defectively designed if "the product fails to perform as safely as an ordinary customer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer." *Pierre v. Intuitive Surgical, Inc.*, 476 F. Supp. 3d 1260, 1270 (S.D. Fla. 2020) (internal quotation marks omitted). Under the risk-utility test, a product is unreasonably dangerous "if the risk of danger in the design outweighs the benefits." *Id.* at 1271. And under the reasonable-alternative-design test, a design is defective where "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonable safe." *Id.* at 1273 (alteration in original) (internal quotation marks omitted).

Pointing to various allegations in the complaint, the Milanas respond that their allegations sufficiently state that Belviq was defective under the consumer-expectations test or, alternatively, the risk-utility test or the reasonable-alternative-design test. Doc. 31 at 8–11. They argue that the allegations state that Belviq was defectively designed because it causes cancer, as demonstrated by the internal studies and supported by the medical literature and the communications of Eisai and Arena with regulatory bodies. *Id.* at 11. They also contend that the complaint proceeds "one step further and actually identifie[s] the defect in design—the defect was that Belviq was a selective serotonin 5HT2c receptor." According to the Milanas, if Eisai and Arena had designed a weight-loss drug that was not a serotonin receptor agonist, Mary's cancer would have been prevented. *Id.* In its reply, Eisai reiterates that the Milanas fail to identify any defect in Belviq's design or "demonstrate" a causal connection between that defect and the alleged injury. Doc. 39 at 2–4.

Although the parties address Counts I and II together, the Court will address the claims separately.

i. Count I (Negligence)

The elements of negligence under a design-defect theory are: (1) the defendant owed the plaintiff a duty of care; (2) the defendant breached that duty; (3) the breach was the proximate cause of plaintiff's injuries; and (4) the product was defective or unreasonably dangerous. *Marzullo v. Crosman Corp.*, 289 F. Supp. 2d 1337, 1342 (M.D. Fla. 2003); *Shapiro v. NuVasive, Inc.*, No. 19-23163-Civ, 2019 WL 5742159, at *2 (S.D. Fla. Nov. 5, 2019). "In the context of medications, a plaintiff identifies a design defect

when she alleges that an ingredient in the drug could have caused the dangerous condition." *Scala v. Eisai, Inc.*, No. 5:21-cv-210-ACC-PRL, 2021 WL 5935588, at *3 (M.D. Fla. Dec. 14, 2021) (holding that the plaintiff stated a claim for negligence based upon a design-defect theory). "A plaintiff's allegations are also sufficient when they put the defendant on notice of the type of harm allegedly caused by the design defect." *Id.* (citing *Small v. Amgen*, 2 F. Supp. 3d 1292, 1297 (M.D. Fla. 2014)). "At the complaint stage, plaintiffs bringing products liability claims are only required to allege the existence of a defect." *In re Monat Hair Care Prods. Mktg., Sales Pracs., & Prods. Liab. Litig.*, No. 18-MD-02841, 2019 WL 5423457, at *3 (S.D. Fla. Oct. 23, 2019) (analyzing strict-liability and negligence claims based upon products that were allegedly defective in their design, manufacture, and warnings).

Taking the Milanas' allegations as true and considering the allegations in the light most favorable to the Milanas, they plausibly allege that Belviq was defective because lorcaserin tended to cause cancer. According to the Milanas, the two-year carcinogenicity study in rats identified lorcaserin as a carcinogen that induced multiple tumor types. The study revealed an increase in tumors in the mammary tissue of both sexes and in female rats at all doses. The same study also demonstrated an increase in astrocytomas, malignant schwannomas, hepatocellular adenoma and carcinoma, skin subcutis fibroma, skim squamous carcinoma, and breast follicular cell adenoma in male rates. Similarly, they allege that the mice study demonstrated an increase in malignant hepatocellular carcinoma in male mice and schwannoma in female mice, which "provide[s] context and support" for lorcaserin qualifying as a carcinogen. Doc.

1 ¶68. And during the readjudication, lorcaserin still increased the incidence, tumor onset and multiplicity, and lethality of mammary adenocarcinoma. They also allege that the FDA announced that an analysis of the CAMELLIA-TIMI 61 data indicated an imbalance of cancer in patients taking Belviq that increased with treatment duration. The FDA also allegedly instructed healthcare professionals to cease prescribing the medication and to contact their patients to inform them of the increased risk of cancer and ask them to stop taking the medication. Finally, the Milanas allege that Belviq, a serotonin 5HT2c receptor agonist, "affect[s] the serotonin pathway," but scientific literature and publications demonstrate that the serotonin pathway can "cause or stimulate" cancer; a safer, feasible alternative to Belviq was a drug that did not affect the serotonin pathway. *Id.* at ¶¶70, 115.

The Milanas also place Eisai and Arena on notice of the type of harm that Belviq allegedly caused. They allege that, as a result of using Belviq, Mary "was caused to suffer from breast cancer." *Id.* at ¶17. They allege that Eisai and Arena breached their duties to the Milanas "by failing to exercise ordinary care in the designing . . . of Belviq . . . in that Eisai and Arena knew or should have known that Belviq created a high risk of unreasonable, dangerous side effects, including cancer . . . ." *Id.* at ¶226. And this negligence in defectively designing Belviq, they claim, was the proximate cause of Mary's "injuries, harm, and economic loss" that she has suffered and will continue to suffer. *Id.* at ¶140.

The factual allegations above provide factual support for these allegations: the trials identified lorcaserin as a carcinogen that induced multiple tumor types, including

an increase in mammary tumors; during the readjudication, lorcaserin still increased the incidence, tumor onset and multiplicity, and lethality of mammary adenocarcinoma; the FDA announced that the CAMELLIA-TIMI 61 data indicated an imbalance of cancer in patients taking Belviq that increased with treatment duration; and the FDA instructed healthcare professionals to cease prescribing the medication and to contact their patients to inform them of the increased risk of cancer and ask them to stop taking the medication. As such, the Milanas allege that Eisai and Arena knew or should have known that lorcaserin was a carcinogen. *Id.* at ¶¶69, 71, 84.

Taking as true these factual allegations about lorcaserin's carcinogenic effects and the FDA's actions following its analysis of the CAMELLIA-TIMI 61 data, and considering those allegations in the light most favorable to the Milanas, shows that the complaint plausibly alleges causation for the negligence claim. Further, Eisai's argument that the Milanas allege only that human trials indicated an imbalance in pancreatic, colorectal, and lung cancer, and therefore fail to allege that Belviq can cause *breast* cancer, ignores these factual allegations. The argument also misinterprets the complaint: the Milanas allege that the FDA reported that the analysis of the CAMELLIA-TIMI 61 data indicated an imbalance of cancer in patients taking Belviq that increased with duration, *including* (and, thus, not limited to) pancreatic, colorectal, and lung cancer. Of course, whether the Milanas can prove causation is a question for a later stage of the litigation. *See In re Monat Hair Care Prods.*, 2019 WL 5423457, at *4 ("Plaintiffs might have a difficult time proving that the Products, and not a pre-existing

medical condition or simple aging, caused their injuries. But, at this stage of the litigation, the Plaintiffs' allegations are sufficient to establish causation.).

As such, the Milanas plausibly allege causation and that the product was defective in Count I to the extent that the Milanas bring the claim under a design-defect theory. Thus, the Court will deny the Partial Motion to Dismiss as to Count I.

ii. Count II (Strict Products Liability-Defective Design and Failure to Warn)

"[T]here are three elements to a strict liability products claim under Florida law: (1) a relationship between the defendant and the product; (2) a defect which caused the product to be unreasonably dangerous; [and] (3) causation between the defect and the harm suffered by the user." *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 607 (11th Cir. 2008); *see Pinchinat v. Graco Children's Prods., Inc.*, 390 F. Supp. 2d 1141, 1148 (M.D. Fla. 2005) ("Under Florida law, a strict product liability action based upon design defect requires the plaintiff to prove that (1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5) injury.") Because Eisai addresses Counts I and II together, it raises the same arguments for this claim as above.

Given the extensive briefing on the issue, the Court will first address the different design-defect theories. In *Aubin v. Union Carbide Corporation*, the Florida Supreme Court held that the Restatement (Second) of Torts, which applies the consumer-expectations test, is the appropriate test for determining a design defect because that test "is more closely aligned with the policy reasons behind Florida's adoption of strict liability in products design cases." 177 So. 3d 489, 502 (Fla. 2015).

The court disapproved the Third District Court of Appeal's adoption of the risk-utility test for design defects, as articulated in the Restatement (Third) of Torts, concluding that the Third Restatement's approach "is inconsistent with the rationale behind the adoption of strict products liability." *Id.* at 494, 510. The court held that a plaintiff is permitted, but not required, "to demonstrate the feasibility of an alternative safer design and that the defendant may present evidence" that such reasonably alternative designed existed. *Id.* at 511.

Although the parties focus on the different design-defect theories, no party has provided, nor has the Court located, any binding authority that requires the Court to determine whether allegations are sufficient under one particular theory at the pleading stage of the litigation. As explained in the case upon which Eisai relies in setting forth these theories, courts "use at least one of the . . . 'tests' to *determine* whether a product is defectively designed . . . ." *Pierre*, 476 F. Supp. 3d at 1270 (emphasis added). In ruling upon the defendant's motion for summary judgment, that court explained that "[a] plaintiff may *prevail* by *proving* either theory." *Id.* (emphasis added) (internal quotation marks omitted). But in ruling upon a motion to dismiss under Rule 12(b)(6), the Court analyzes only whether a plaintiff's claims are plausible, not whether the plaintiff can prove her claims. As such, the Court need not determine whether the Milanas' allegations are sufficient under one particular design-defect theory. *See*, *e.g.*, *Aubin*, 177 So. 3d at 520 (quashing the appellate court's reversal of a final judgment following a trial); *Cavanaugh v. Stryker Corp.*, 308 So. 3d 149, 155 (Fla. 4th DCA 2020) (holding that the trial court did not abuse its discretion in withholding the plaintiff's

proposed jury instruction about the consumer-expectations test); *Pierre*, 476 F. Supp. 3d at 1270 (analyzing the theories in ruling upon a summary judgment motion); *Messina v. Ethicon, Inc.*, No. 6:20-cv-1170-PGB-LRH, 2021 WL 1329072, at *4 (M.D. Fla. Mar. 31, 2021) (same).

Eisai argues that the Milanas insufficiently allege a defect in Belviq. Again, the Milanas' allegations detail the trials that identified lorcaserin as a carcinogen; that lorcaserin still increased the incidents, tumor onset and multiplicity, and lethality of mammary adenocarcinoma during the readjudication; the FDA's announcement about the CAMELLIA-TIMI 61 data reflecting an imbalance of cancer; and the FDA's instructions to healthcare professionals about the increased risk of cancer and to cease taking the medication. The Milanas also allege that, based upon the allegations about the rat study, the mouse study, and the readjudication, Belviq is an unsafe product and an unreasonably dangerous product. Doc. 1 ¶¶69, 71 84. Taking the allegations as true and viewing them in the light most favorable to the Milanas, the Milanas plausibly allege a design defect. *See*, *e.g.*, *Hosler v. Alcon Labs., Inc.*, No. 12-60025-CIV, 2012 WL 4792983, at *7 (S.D. Fla. Oct. 9, 2012) (holding that the plaintiff plausibly alleged a defect where he asserted the design of the drug "resulted in corneal scarring when used for treatment post-PRK surgery"); *Krywokulsi v. Ethicon, Inc.*, No. 8:09-CV-980-JSM-MAP, 2010 WL 326166, at *2–3 (M.D. Fla. Jan. 21, 2010) (holding that the plaintiff plausibly alleged a defect where he alleged that "the defective patches delaminated and/or malfunctioned, thus making the patches unsafe and dangerous for use"); *In re Monat Hair Care Prods.*, 2019 WL 5423457, at *4 (holding that the

plaintiffs plausibly alleged a defect where they alleged that the products were "defective in design because they contain[ed] ingredients—Cocamidopropyl Betaine, Benzyl Alcohol, Red Clover Leaf Extract, Butylene Glycol, and sulfates," which were "known to cause allergic reactions and defects").

Eisai contends that the complaint lacks allegations indicating how any design defect caused her breast cancer. Doc. 19 at 8; Doc. 39 at 3–4. But the Milanas allege that Mary suffered from breast cancer as a result of using Belviq and that Belviq's defective design was a substantial factor in causing, and a proximate cause of, Mary's injuries. Doc. 1 ¶¶17, 180–82. Viewing these allegations together with the factual allegations above reveals that the Milanas plausibly allege that Belviq's defective design proximately caused her injuries. And for the reasons stated above, Eisai's argument that the complaint lacks allegations that Belviq can cause breast cancer is unavailing.

Thus, the Milanas plausibly allege causation and that the product was defective in Count II to the extent that the Milanas bring the claim under a design-defect theory. Therefore, the Court will deny the Partial Motion to Dismiss as to this claim.

B. Counts IV (Fraudulent Misrepresentation and Concealment) and V (Negligent Misrepresentation) Fail to Meet the Heighted Pleading Standard under Rule 9(b)

Eisai also argues that Counts IV (Fraudulent Misrepresentation and Concealment) and V (Negligent Misrepresentation) fail to meet the heightened pleading standard under Rule 9(b). The Court agrees.

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To satisfy Rule 9(b), a complaint must allege "facts as to time, place, and substance of the defendant's alleged fraud, specifically the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1222 (11th Cir. 2012) (internal quotation marks omitted). A plaintiff satisfies the heightened pleading standard of Rule 9(b) where she alleges: "(1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the contents of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud." *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1371 (11th Cir. 1997) (internal quotation marks omitted). A complaint does not meet Rule 9(b) where a plaintiff lumps together the defendants in alleging fraud. *Ambrosia Coal & Constr. Co. v. Pages Morales*, 482 F.3d 1309, 1317 (11th Cir. 2007). A plaintiff must allege facts with respect to each defendant's alleged participation in the fraud. *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1291 (11th Cir. 2010).

Eisai asks the Court to dismiss Count IV and Count V, arguing that the allegations for those claims fail to meet the pleading standard of Rule 9(b). Doc 19 at 10–11. Eisai argues that the Milanas fails to allege with particularity the time when the allegedly fraudulent statements or omissions occurred, the specific contents of the

allegedly fraudulent statements or omissions, and who is responsible for the allegedly fraudulent statements and omissions. *Id.* at 11.

First, in response to Eisai's argument that they insufficiently allege who is responsible for the allege fraud, the Milanas identify "Defendants" as the entities who made the fraudulent misrepresentations and concealments. Doc. 31 at 16–17. To that end, the Milanas point to several allegations in their complaint in support. *Id.* As the Milanas' argument acknowledges, they lump Eisai and Arena together when discussing the alleged fraud without specifying the defendant who is responsible for each misrepresentation or omission. As such, Counts IV and V fall short of the particularity standard under Rule 9(b). *See*, *e.g.*, *Brooks*, 116 F.3d at 1381 (holding that the plaintiff failed to plead with particularity when it lumped the defendants together in the fraud allegations); *Merino v. Ethicon, Inc.*, 536 F. Supp. 3d 1271, 1287 (S.D. Fla. 2021) (holding that the plaintiff failed to satisfy Rule 9(b)'s requirements when the complaint "referred to Defendants generally without identifying the specific persons responsible for misrepresentations"). Thus, Counts IV and V are deficient under Rule 9(b) in this respect.

Next, as to Eisai's argument as to the substance—the "what"—of the alleged fraud, the Milanas argue that Eisai and Arena made these misrepresentations with knowledge of their falsity: (1) Belviq was safe to use; (2) Belviq was effective to use as a weight-loss adjunct; and (3) Belviq's efficacy outweighed any safety risk. Doc. 31 at 17. The Milanas further argue Defendants concealed the following: (1) that Belviq was not safe to use because of its increased risk of cancer; (2) that Belviq was not efficacious

as a weight loss adjunct; and (3) that Belviq's safety risks outweighed its efficacy. *Id.* In conjunction, the Milanas argue these misrepresentations and concealments occurred by way of internet advertisements, "Defendants' website for Belviq," "Belviq's product information sheet between August 2013 and August 2020," and Belviq's label "in 2013 and thereafter." *Id.* at 17–18.

Indeed, the allegations supporting Counts IV and V tie the alleged false representations of Eisai and Arena to internet advertisements, the website, Belviq's patient information sheet, and Belviq's label. Doc. 1 ¶¶239, 241, 243, 245, 252, 262, 270–72, 284–85, 327, 330–32, 337–38. The Milanas also tie the alleged concealments for Count IV to these sources of information. *Id.* at ¶¶253–54, 257–58, 262–63, 266–67, 273–74, 279–80, 282, 286–87 290–91. For example, they allege that the representations on the website relating to Belviq "were false and/or fraudulent in that Defendants concealed from [Mary] that Belviq was associated with an increased risk of cancer." *Id.* at ¶266. By way of another example, they allege, upon information and belief, that "Defendants concealed from Dr. Wei by way of the product label that Belviq was associated with an increased risk of cancer." *Id.* at ¶273.

But here's the problem: the Milanas fail to allege "precisely what statements were made in what documents . . . or what omissions were made" or "the contents of such statements . . . ." *Brooks*, 116 F.3d at 1371. The Milanas only vaguely reference the internet advertisements, the website, the patient information sheet, and the label, without specifying the representations in, or the contents of, those sources of information. The result is a lack of particularity under Rule 9(b). *See*, *e.g.*, *Kendall v.*

Bos. Sci. Corp., No. 6:17-cv-1888-RBD-GJK, 2018 WL 3343239, at *3 (M.D. Fla. June 25, 2018) ("But these allegations lack the requisite particularity of Rule 9(b). Kendall does not identify *what* information the advertisement conveyed."); *Byrnes v. Small*, 142 F. Supp. 3d 1262, 1270 (M.D. Fla. 2015) (holding that the plaintiffs identified with sufficient precision which false statements were made when they quoted the alleged misrepresentations and paraphrased them in her own words); *see also Bailey v. Janssen Pharmaceutica, Inc.*, No. 06-80702-CIV, 2006 WL 3665417, at *6 (S.D. Fla. Nov. 14, 2006) ("The allegation that Johnson & Johnson represented that the patch was 'safe' for the relief of postsurgical pain i[s] overly broad and vague" for purposes of Rule 9(b)), *aff'd*, 536 F.3d 1202 (11th Cir. 2008). And because the concealments are grounded in those sources of information or the representations therein, the alleged concealments do not satisfy Rule 9(b), either.

Finally, in response to Eisai's argument about the time when the fraudulent statements or omissions occurred, the Milanas point to a period of time stretching from August of 2013 to 2020. Doc. 31 at 18.[6] Alleging that the purported fraud occurred at some point, or points, during a seven-year period of time does not identify the time of the fraud with the requisite particularity. *See Kaufman v. Wyeth Co.*, No. 02-22692-CIV, 2011 WL 10483568, at *5 (S.D. Fla. Apr. 12, 2011) (holding that a thirty-year period of misrepresentations and omissions was insufficient under Rule 9(b)'s heightened

[6] Although the Milanas point to this seven-year timeframe, the Milanas also allege that the representations occurred in 2012 or "in or about 2012 or 2013." Doc. 1 ¶¶239, 327. Thus, the alleged time period may extend beyond 2013 to 2020.

standard); *see also Scaturro v. Seminole Cas. Ins. Co.*, 542 F. Supp. 2d 1290, 1299 (S.D. Fla. 2008) (holding that the plaintiff failed to meet the 9(b) standards of pleading where, in relevant part, the plaintiff vaguely alleged that conversations occurred between him and the defendant regularly between May 2002 and early-2007). Allowing these claims to proceed as pleaded would require Eisai and Arena to search through at least seven years of Belviq internet advertisements, websites, patient information sheets, and labels to discern which statements could be the subject of the Milanas' claims; this is inadequate notice, especially in conjunction with the other deficiencies under Rule 9(b). *See Brooks*, 116 F.3d at 1381 (describing fair notice as the "most basic consideration" underlying Rule 9(b)). The failure to distinguish between Eisai and Arena, along with the other deficiencies, frustrates any attempt to understand the connection between the provided sources of information and Eisai. Thus, Counts IV and V are deficient under Rule 9(b) in this respect, too.

In sum, the Milanas fail to plead Counts IV and V with particularity under Rule 9(b). Given Rule 15's liberal amendment policy, the Court will grant the Milanas leave to amend those claims to satisfy Rule 9(b). *See* Fed. R. Civ. P. 15(a)(2) (stating that a "court should freely give leave when justice so requires").

V. CONCLUSION

The Court will grant-in-part and deny-in-part Eisai's Partial Motion to Dismiss and dismiss Counts IV and V, without prejudice, to the Milanas' right to amend. Further, the Court will deny Arena's Motion to Dismiss.

Accordingly, it is hereby **ORDERED**:

1. Defendant Eisai, Inc.'s Partial Motion to Dismiss Plaintiffs' Complaint (Doc. 19) is **GRANTED-IN-PART** and **DENIED-IN-PART**. Count IV (Fraudulent Misrepresentation and Concealment) and Count V (Negligent Misrepresentation) are **DISMISSED**, **without prejudice**, to the right of Plaintiffs Mary Milana and Victor Milana to amend those claims. In all other respects, the Partial Motion to Dismiss is **DENIED**.
2. Defendant Arena Pharmaceuticals, Inc.'s Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(6) and 9(b) (Doc. 21) is **DENIED**.
3. The Court grants Plaintiffs Mary Milana and Victor Milana leave to file an amended complaint that corrects the deficiencies identified in this order within **FOURTEEN (14) DAYS** of the date of this order. Failure to file an amended complaint will result in Counts IV and V being dismissed and this action proceeding as to the Milanas' remaining claims, excluding the breach of express warranty claim.

DONE AND ORDERED in Tampa, Florida on March 22, 2022.

Charlene Edwards Honeywell
Charlene Edwards Honeywell
United States District Judge

Copies to:
Counsel of Record and Unrepresented Parties, if any